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SECTION 7

510 (k) SUMMARY

The following information summarizes the safety and effectiveness information upon which the substantial equivalence determination for the Tornier Ankle Arthrodesis Plate System is based.

Prepared:	Friday, December 05, 2008
Applicant:	Tornier, Inc. 3601 West 76th Street Suite 200 Edina, MN 55435 **Registration Number:** 9100540
Telephone:	978-232-9997
Fax:	978-232-9998
Contact:	Brahim Hadri (Sr. Regulatory Affairs Specialist (RAC US))
Device Name:	Ankle Arthrodesis Plate System
Device Trade Name:	(tbd)
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	888.3030, Single/multiple component metallic bone fixation appliances and accessories
Product Code:	HRS
Predicate Devices:	The Tornier Ankle Arthrodesis Plate System includes 3 types of plates. • An Anterior Tibio-Talar Plate, • A Lateral Tibio-Talar-Plate, • And a Lateral Tibio-Talar-Calcaneal Plate: The *Anterior Tibio-Talar Plate* is substantially equivalent to the Synthes LCP Ankle Arthrodesis Plate, K061940. The *Lateral Tibio-Talar Plate* is substantially equivalent to the Synthes LCP Ankle Arthrodesis Plate, K061940, and the Newdeal TTC Plates, K060473. The *Lateral Tibio-Talar-Calcaneal Plate* is substantially equivalent to the Newdeal TTC Plates, K060473.

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SECTION 7

510 (k) SUMMARY (continued)

Device Description
The Tornier Ankle Arthrodesis Plate System consists of minimally contoured plates, screws and washers. Reusable instruments are provided to facilitate fixation in total ankle arthrodesis and fracture fixation, fusion, and osteotomy of the bones of the foot. The Ankle Arthrodesis Plate System is made of stainless steel material or titanium material.

The Tornier Ankle Arthrodesis Plate System plates are not differentiated for Right or Left sides. The system includes an Anterior Tibio-Talar Plate (two sizes, plus an optional augmentation plate), a Lateral Tibio-Talar Plate (three sizes), and a Lateral Tibio-Talar-Calcaneal Plate (three sizes). The screws are provided in one diameter and in various lengths. The washers are provided in one size.

The system consists of sheaths that are attached to the bone plate by screws to cover the bone screws in bone plates. The osteosynthesis screws are driven into the bone through holes in the plates.

Indications for Use
The Tornier Ankle Arthrodesis Plate System is intended for arthrodesis of the ankle joint and distal tibia, fractures, osteotomies, and fusions of small bones including the foot and ankle.

Conclusion:
The Tornier Ankle Arthrodesis Plate System is substantially equivalent to commercially marketed devices, the Synthes LCP Anterior Ankle Arthrodesis Plate, K061940 and the Newdeal Advansys™ T.T.C.P. (Tibio Talo Calcaneus Plate) K060473;
The Tornier Ankle Arthrodesis Plate System does not raise any new issues of scientific technology, safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

OCT 2 7 2009

Tornier, Inc
% Mr. Brahim Hadri
100 Cummings Center, Suite 444C
Beverly, MA 01915

Re: K090139
Trade/Device Name: Tornier Ankle Arthrodesis Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: September 16, 2009
Received: September 16, 2009

Dear Mr. Hadri:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

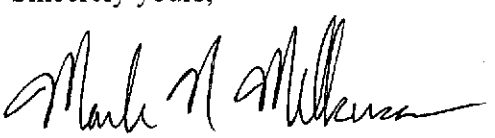
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 6
Indications for Use Statement

Indications for Use

510(k) Number (if known): ~~N/A~~ K090139

Device Name: Ankle Arthrodesis Plate System

Indications for Use:

The Tornier Ankle Arthrodesis Plate System is intended for arthrodesis of the ankle joint and distal tibia, fractures, osteotomies, and fusions of small bones including the foot and ankle.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Janita D for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090139